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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/829,558	03/28/97	MERULO D	8105-009

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EXAMINER	
ZEMAN, R	
ART UNIT	**PAPER NUMBER**
1645	9

DATE MAILED: 12/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/829,558	Merulo et al
Examiner	**Group Art Unit**
Robert A. Zeman	1645

☒ Responsive to communication(s) filed on *Oct 12, 2000* .

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-10, 18-23, and 27-31* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-10, 18-23, and 27-31* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *5*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Response to Amendment

Claims 11-27, 24-26 and 32-47 have been canceled. Claims 1-10, 18-23 and 27-31 are pending and currently under consideration.

Receipt of IDS in Paper No. 5 is acknowledge. It should be noted that all of the cited references could not be located at the time of examination. Consequently, only those references available were considered. The remaining references will be considered when they become available.

Objections to Specification Withdrawn

The objections to the specification for the improper recitation of the address for ATCC, lack of ATCC depository numbers and an improper reference to a U.S. Application Serial Number are withdrawn in light of the amendments thereto.

Claim Rejections Withdrawn

35 USC § 112

The rejection of claims 1-10, 18-23 and 27-31 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the insertion of the particular "ZZ" IgG

binding domain of Protein A into a viral vector, does not reasonably provide enablement for insertion of a **portion** of that domain, or for a **portion** of any IgG binding domain of Protein A.

The rejection of claims 1-10, 18-23, and 27-31 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the insertion of synthetic Protein A IgG "ZZ" binding domain into a full length viral protein, does not reasonably provide enablement for fragments of those viral proteins is withdrawn in light of the amendment thereto.

The rejection of claim 3 under 35 U.S.C. 112, second paragraph, for being rendered vague and indefinite by the use of the phrase "the vector further comprises a portion of the gp70" is withdrawn in light of the amendment thereto.

The rejection of claim 9 under 35 U.S.C. 112, second paragraph, for reciting the limitation "the chimeric gene" in reference to claim 8 is withdrawn in light of the amendment thereto.

The rejection of claims 18-23 under 35 U.S.C. 112, second paragraph, for being rendered vague and indefinite by the use of the term "viral complex" is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

The rejection of claims 1-10, 18-23 and 27-31 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the insertion of the particular "ZZ" IgG binding domain of Protein A into a viral vector, does not reasonably provide enablement for any

other IgG binding domain of Protein A is maintained for reasons of record. The specification does not disclose that any other IgG binding domain, or portion of any other IgG binding domain of Protein A would be useable in the invention. Protein A is known to have at least 4 IgG binding domains, having varying specificity for immunoglobulin. (see Surolia 1982 Trends Biochem. Sci 7:74-76). Consequently, it would not be clear to one of skill in the art whether any natural IgG binding domain, or portion thereof, would be able to function in the same manner as the synthetic ZZ binding domain disclosed in the specification.

35 USC 103

The rejection of claims 1-10, 18-23, and 27-31 under 35 U.S.C. 103(a) as being unpatentable over Barber et al. (US Patent 5,591,624) and Wickham et al. (US Patent 5,846,782), in view of Nilsson et al. (Nilsson et al. 1987 Protein Eng. 1: 107-113) is maintained for reasons of record.

Applicants argue that the literature is "full of failure and false promises" and that the references cited in the aforementioned rejection are merely "invitations to try" and hence are not a proper basis for a rejection under 35 U.S.C. 103(a). Applicant further recites passages from Wickham (Nature Biotechnology, 1997 Vol 15 No. 8, page 717) to bolster the argument that the Wickham et al reference cited by examiner could not provide one of ordinary skill with a reasonable expectation of success. Applicant further argues that Barber fails to provide a description of how to make the claimed invention that can transduce a target cell with high

efficiency and that if Barber et al. "actually provided one of ordinary skill a reasonable expectation of success, Wickham would never have written his glowing article in praise of Applicant's invention". Applicant's arguments have been fully considered and found not to be persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

With regards to Applicant's arguments that Wickham et al. does not provide a basis for rejection since it does not disclose the limitation of "high efficiency" , it should be noted that mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979). Additionally, the fact that Applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985)

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.

DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman

December 20, 2000